



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,716	09/21/2001	Grigoriy S. Tchaga	CLON-060	4277
41064	7590	06/14/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS (BD BIOSCIENCES)			LAM, ANN Y	
1900 UNIVERSITY AVENUE			ART UNIT	PAPER NUMBER
SUITE 200				1641
EAST PALO ALTO, CA 94303				

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,716	TCHAGA, GRIGORIY S.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 and 45 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1, 6-12, 17-19 and 45 is/are rejected.
 7) Claim(s) 2-5 and 13-16 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-12, 17, 18 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Wohlstadter et al., 6,207,369.

Wohlstadter discloses a method of determining whether a sample includes an analyte of interest (col. 8, line 29), said method comprising: contacting said sample with a planar array (i.e., array of binding domains (48) on planar electrode (50), see figure 3, and col. 8, lines 5-11, and also col. 59, lines 64-66) of a plurality of distinct binding agents (i.e., binding domains 48) displayed on a surface of a solid support (i.e., electrode 50) wherein each of said binding agents at least comprises a specific epitope binding domain of an antibody (col. 24, lines 24-27);

detecting the presence of any resultant binding complexes on said surface to obtain analyte binding data (col. 27, line 26);

and employing said analyte binding data to determine whether said sample includes said at least one analyte of interest (col. 27, line 26.)

Art Unit: 1641

method provides a sensitivity of at least 10pg/ml of analyte of interest when the analyte is directly fluorescently labeled (col. 26, line 22, and col. 38, line 46.)

As to claims 6 and 45, said method further comprises extracting said at least one analyte from a cellular source (col. 18, lines 11-13) and labeling said extracted at least one analyte (i.e, labeling with labeled secondary antibodies, col. 38, line 45), wherein said extracting and labeling steps employ the same buffer composition (col. 80, line 66) Since Applicant has not specifically defined how the extracting step is carried out, Examiner interprets the step of adding buffer (in col. 80, line 66) as part of the extracting step.

As to claim 7, said buffer composition is free of components that include primary amine moieties (see for example col. 95, lines 27-28.)

As to claim 8, said buffer composition has a pH ranging from about 7 to about 12 (col. 91, line 33.)

As to claim 9, said buffer composition is capable of extracting at least about 95% of the proteins of an initial cellular source (col. 95, lines 27-28.)

As to claim 10, said at least one analyte is a protein (col. 24, line 26.)

As to claim 11, said method comprises determining the presence of at least two distinct analytes (col. 8, line 6 and 23) in said sample.

As to claim 12, said method comprises a plurality of washings steps between said contacting and detecting steps (col. 91, lines 30-35.)

As to claim 17, the method is considered a method of determining a protein expression profile for the sample, since it is a method of determining the presence of a protein in a biological fluid sample such as whole blood (col. 18, lines 11-13.)

As to claim 18, said method further comprises a sample fractionating step prior to said contacting step (i.e., use of filter for removing cells from blood, col. 44, lines 21-22.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter et al., 6,207,369, in view of Moyer et al., 3,791,933.

Wohlstadter discloses the invention substantially as claimed (see above). More specifically Wohlstadter teaches that a filter may be included for removing cells from blood prior to the assaying steps (col. 44, lines 21-24.) This is considered to be the fractionating step in Applicant's claims. However Wohlstadter does not teach that the fractionating step comprises contacting a sample with at least one affinity column.

Moyer discloses that a stacked array of filter discs confined in a column which is adapted for placement of a fluid test media may be used to filter out blood cells from a

test sample in an assay for the detection of an analyte (col. 3, lines 51-52, and col. 9, lines 34-56.)

It would have been obvious to one of ordinary skill in the art to substitute the stacked filter discs taught by Moyer for the membrane in Wohlstadter as a functional equivalent since both are used to filter out blood cells from a test sample in an assay for the detection of an analyte.

Allowable Subject Matter

Claims 2-5; 13-16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's argument with respect to the 112, second paragraph is moot because the rejection is hereby withdrawn.

Applicant's arguments filed March 21, 2005 with respect to the rejected claims above have been fully considered but they are not persuasive.

Applicant argues that the passages cited by Examiner do not in fact teach the sensitivity element of the claimed invention. Examiner reasserts that because Wohlstadter uses the same reagents as in the claimed method, the same level of sensitivity (i.e., 10 pg/ml) will be achieved. (Examiner also notes that Applicant has not

Art Unit: 1641

claimed what particular binding agents are used, but rather has only claimed fluorescent labeling.)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/10/05